§170.315(f)(4) Transmission to cancer registries

2015 Edition Test Procedure

Version 1.2 Updated on 04-28-2016

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016
1.1	Removed the reference to Juror Document in paragraph (f)(4)(i) Test Lab Verification step 3.	03-21-2016
1.2	Inserted reference to the Juror Document now available.	04-28-2016

Regulation Text

Regulation Text

§170.315 (f)(4) *Transmission to cancer registries—*

Create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(i)(2).

(ii) At a minimum, the versions of the standards specified in §170.207(a)(4) and (c)(3).

Standard(s) Referenced

Paragraph (f)(4)(i)

§ 170.205(i)(2) HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1, April 2015

Paragraph (f)(4)(ii)

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015

Release

§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

Please consult the Final Rule entitled: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Testing components

Paragraph (f)(4)(i)

System Under Test

1. The user enters the cancer information for each of the test cases referenced from the Home Tab of the CRV. All test cases are required. Note that health IT developers should select the appropriate test case for Test Case 1, based on their module's capability.
2. The Health IT Module creates a cancer case document based on the standard specified in § 170.205(i)(2) HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1.1 for each test case as outlined below:

Modules that collect radiation treatment data:

- Test_Case_1a_Complete_Record_With_Radiation

Modules that do not collect radiation treatment data:

- Test_Case_1b_Complete_Record_Without_Radiation

ALL Health IT Modules :

- Test_Case_2_Cancer_Diagnosis_With_No_Treatment
- Test_Case_3_Two_Cancer_Diagnoses
- Test_Case_4_Two_Cancer_Diagnoses_Update
- Test_Case_5_Non-reportable

Test Lab Verification

1. The tester verifies that the Health IT Module includes the source cancer information correctly and without omission through visual inspection, using the test data associated with the selected test case.
2. The tester imports the cancer reports into the test tool for validation based on each test case listed, and uses the Validation Report produced by the test tool to verify the report indicates passing without error to confirm that the cancer report is conformant to the standard specified in § 170.205(i)(2).
3. The tester verifies that the Health IT Module's supplied cancer document in step 2 is accurate and without omission using the Context-based Validation Report, the Juror Document, and through additional visual inspection, checking for equivalent text for:
   a. content for all section level narrative text; and
   b. display names: if the context-based validation indicates a mismatch, equivalent entries are allowable.
4. Negative Test: For Test_Case_5_Non-reportable, the tester verifies using Documentation that the non-reportable test case does not generate a CDA report.

Paragraph (f)(4)(ii)

System Under Test

The cancer case information is in accordance with § 170.207(a)(4) SNOMED CT® and § 170.207(c)(3) LOINC®.

Test Lab Verification

The tester uses visual inspection of the Health IT Module configuration file or Documentation to verify cancer case information are represented using the named § 170.207(a)(4) standard and the named § 170.207(c)(3) standard.

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